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ROBERT E. HANSON
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVENUE
SUITE 2400
AUSTIN, TX 78701

EXAMINER

FOX, DAVID T

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1638

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**BEFORE THE BOARD OF PATENT APPEALS ~~TECH CENTER 1600/2000~~
AND INTERFERENCES**

Paper No. 02172004

Application Number: 10/000,311
Filing Date: December 4, 2001
Appellant(s): GRIFFITH, W.D.

Robert E. Hanson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04 December 2003.

- I. A statement identifying the real party in interest is contained in the brief.

Art Unit: 1638

II. A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

III. The statement of the status of the claims contained in the brief is correct.

IV. No amendment after final has been filed.

V. The summary of invention contained in the brief is correct.

VI. The Appellant's statement of the issues in the brief is correct.

VII. Grouping of the Claims

Appellant's brief includes a statement that the claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

VIII. The copy of the appealed claims contained in the Appendix to the brief is correct.

IX. Listing of the prior art.

5,523,520

Hunsperger et al.

06-1996

Eshed et al. "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato" Genetics, Vol. 143, (August 1996), pp. 1807-1817.

Kraft et al. "Linkage Disequilibrium and Fingerprinting in Sugar Beet" Theoretical and Applied Genetics, Vol. 101 (2000), pp. 323-326

X. Grounds of Rejection

35 USC 112, second paragraph

Claims 6 and 26-28 on appeal stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention. Appellant's statement on page

19 of the Brief, top paragraph, that the indefiniteness rejection of claim 8 is not being contested, is noted.

In claim 6: the recitation “further defined as comprising a gene conferring male sterility” renders the claim indefinite. The recitation appears to broaden the scope of its parent claim, or to raise some doubt as to whether the corn plant of claim 6 must be male sterile. The specification does not define plants expressing all the physiological and morphological characteristics of LH321 as being male sterile, or as comprising a gene that confers male sterility; in fact, the plant of claim 2 (from which claim 6 depends) is male fertile. Thus claim 6 cannot incorporate all the limitations of claim 2 because it is directed to a plant that is not male fertile. It is suggested that the claim be amended to recite that the plant was produced from the plant of claim 2 and to indicate how the gene conferring male sterility was introduced into the plant of claim 6.

Appellant’s Argument and Examiner’s Response:

Appellant argues that the claim is a proper dependent claim that specifies an additional characteristic, specifically, “a gene conferring male sterility”, which is not in the independent claim. Appellant argues that claim 6 therefore contains a reference to the parent claim, contains a further limitation of the subject matter claimed in the main claim, and incorporates all elements of the claim from which it depends, and is therefore in proper dependent form pursuant to 37 CFR 1.75(c) (Appeal Brief, page 19, first and second full paragraphs).

However, claim 6 does not incorporate all elements of the parent claim. The plant of parent claim 2, LH321, is male fertile. See pages 9-10 of the specification;

particularly page 10, paragraph [0050], where the plant is characterized as having heavy pollen shed (rated as 7 on a scale from zero being male sterile to 9 being heavy pollen shed). The plant of claim 6, however, is not male fertile. Therefore, claim 6 does not incorporate all elements of the claim from which it depends. Further, as the plant of claim 2 is male fertile, it is contradictory to say that claim 6 incorporates all elements of claim 2, yet is directed to a plant that is not male fertile.

The following amendments are suggested: introduce a new claim 33 that reads, --A method of producing a male sterile corn plant comprising transforming the plant of claim 2 with a nucleic acid molecule that confers male sterility.--, and a new claim 34 that reads, --A male sterile corn plant produced by the method of claim 33.--

In claim 26: the recitation "corn plant ...of claim 2...wherein the plant...[has] been transformed so that its genetic material contains one or more transgenes" renders the claim indefinite. The recitation appears to broaden the scope of claim 2, or raises some doubt as to whether the plant has all of the traits expressed by the plant of claim 2. Since claim 2 is drawn to a plant with defined characteristics and genotypes which exclude the presence of introduced transgenes, it is confusing to characterize these plants as comprising additional genes. Dependent claims 27-28 fail to remedy the deficiency of claim 26.

Appellant's Arguments and Examiner's Response:

Appellant argues that the recited limitation is in addition to that of the main independent claim. Appellant argues that the transgene is added to and modifies the plant recited in the independent claim, that claim 26 contains a reference to the parent

claim, contains a further limitation of the subject matter claimed in the main claim, and incorporates all elements of the claim from which it depends (Appeal Brief, page 19, first and second full paragraphs).

However, claim 26 adds an additional transgene, and possibly an additional trait expressed by that transgene, to the plant of claim 2. For example, the transgene may confer increased resistance against insects. The plant of claim 2 may be susceptible to insect damage, while the plant of claim 26, because of the additional transgene, would be resistant to insects. Or the transgene may confer the trait of male sterility on the plant, whereas inbred corn plant LHh321 is male fertile. Thus, it is unclear if the plant of claim 26 has all of the traits possessed by the plant of claim 2.

35 USC 112, first paragraph, written description

Claims 6, 12-19, 21, 24, 26-28 and 30-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any hybrid corn seed produced by the process of crossing the inbred corn plant LH321 with any second, distinct, inbred corn plant, and any hybrid corn plant produced by growing said hybrid corn seed (claims 12-16); methods of using the hybrid (claims 17-18); methods of repeatedly crossing LH321 with any other undefined non-LH321 parent over multiple generations (claims 19, 21,

24 and 30-31); any inbred corn plant produced by growing seed of inbred corn plant LH321, wherein said plant further comprises any transgene of any sequence and conferring any trait (claims 26 and 28); a method of producing a transgenic corn plant comprising crossing a corn plant which has been transformed with any transgene of any sequence and conferring any trait (claim 27); and any inbred corn plant which comprises any gene of any sequence which confers male sterility (claim 6). Claim 31 is also drawn to the use of a multitude of molecular markers, i.e. small pieces of DNA which are adjacent to/correlated with the presence of a particular gene conferring a particular trait, including restriction fragment length polymorphisms.

The specification describes numerous morphological and physiological characteristics of inbred corn plant LH321 (page 9, paragraph [0042] through page 12, line 3). The specification indicates that access to the seeds of the instantly claimed inbred line, currently maintained by Holden's Foundation Seeds, Inc., will be available to those entitled thereto under 37 CFR 1.114 and 35 USC 122, and that all restrictions upon the public availability of the seeds will be irrevocably removed upon allowance (see page 34, paragraph [0153]). The response of 21 April 2003 indicates that a deposit of 2500 seeds of LH321 will be made with the American Type Culture Collection, in accordance with the requirements of 37 CFR 1.801-1.809 (see the paragraph bridging pages 4 and 5 of the response). The specification also compares performance data for four hybrids made by crossing LH321 with each of four different and genetically uncharacterized inbreds, namely inbreds HC33, LH227, LH200 or LH303 (pages 31-33).

A review of the full content of the specification indicates that seed of inbred corn plant LH321, and hybrid seed produced by crossing a LH321 plant with any other corn plant, are essential to the operation and function of the claimed invention. A search of seed of inbred corn plant LH321 indicates that it is novel and unobvious.

A review of the language of claims 12-16 indicates that the claims are drawn to a genus, i.e., any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant LH321 with any second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-LH321 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-LH321 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

The specification does not describe any hybrid corn seeds or plants other than the four exemplified hybrids discussed above. There is no evidence on the record of a relationship between the structure of the complete genome of each of these hybrids and the complete genome of other hybrids. There is no evidence on the record of any genetic composition or morphological characteristics of any of the four other inbreds used to make the four exemplified hybrids. The structure of the complete genome of any of the four inbreds was not disclosed; nor was any relationship between the structure of their complete genome and the morphological characteristics of these inbreds. Hybrids produced by crossing LH321 with other, distinct inbred corn plants

would, of course, produce plants that do not express the same traits as LH321; and hybrids produced by crossing LH321 with distinct inbred corn plants other than HC33, LH227, LH200 or LH303 also would not express the same traits as the four exemplified hybrids produced by crossing each of these four inbreds with LH321. The descriptions of LH321 and the four exemplified hybrids do not provide any information concerning the morphological and physiological characteristics of other plants. In view of these considerations, a person of skill in the art would not have viewed the teachings of the specification as sufficient to show that the Appellant was in possession of the claimed genus of hybrid seeds and plants produced therefrom. Furthermore, the skilled artisan would not have recognized Appellant to have been in possession of the claimed methods of using the inadequately described hybrids, as claimed in claims 17-18.

The specification also indicates that single locus converted plants (or "single gene converted plants") are defined as plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus or single gene transferred into the inbred via the backcrossing technique. The first step in the backcrossing process occurs when the exemplified inbred is outcrossed to a genetically distinct plant (the "donor plant" or "non-recurrent parent") which carries a gene or genes conferring a particular trait of interest, i.e. disease resistance. The donor plant may be a weedy relative of corn which contains many undesirable characteristics not suited for agriculture, such as low seed yield. Alternatively, the donor plant may be another commercially derived inbred which is

suited to a different set of agronomic characteristics, i.e. adapted to grow in a different region of the country with different temperatures and different length of growing season. During classical breeding, unlike transformation or genetic engineering, a piece of DNA containing the actual gene conferring the desired trait is not isolated. Instead, a plant exhibiting that trait is identified, and then crossed to the plant of interest, wherein all of the additional genetic components of the donor plant are also transmitted to the progeny plant. Following this outcross to the donor plant, the resultant hybrid containing the desired gene is then repeatedly crossed back to the original inbred, the "recurrent parent", in an attempt to re-introduce the desired genes of the inbred into the progeny plant, and in an attempt to eradicate all of the other undesired genes present in the genome of the donor parent.

A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (or locus) on a plant chromosome. The specification contemplates numerous different single loci involved in expressing various traits (page 28, paragraph [0131 through page 30, paragraph [0133]).

However, the specification provides no description of any plant produced by classical breeding methods such as backcrossing or recurrent selection, as claimed in claim 31. No other corn plant ("donor parent") exhibiting a single desired trait for use in backcross breeding has actually been disclosed and described, and no resulting progeny from such a cross has actually been disclosed or described. Additionally, the remaining genetic complement of the donor parent, which comprises tens of thousands

of other genes, in addition to the gene or genes responsible for the trait of interest, has not been characterized. Furthermore, the individual genes conferring the desired traits have not been characterized, and the genes for several of the contemplated traits, i.e. "enhanced nutritional quality, industrial usage, yield stability and yield enhancement" as recited on page 30 of the specification, line 1, have not been isolated either by Appellant or by the skilled artisan. In fact, the genes conferring such traits are thought to be quantitative in nature, i.e. governed by multiple genes, often occurring on different chromosomes, which additively contribute to the desired effect.

Thus, claim 31 reads on a method for crossing LH321 with a multitude of non-exemplified breeding partners which have not been characterized either morphologically or genetically. The progeny of such a method would contain varying amounts of non-LH321 genetic material contributed by the non-LH321 parent(s). This non-LH321 genetic material would alter the expression of the traits expressed by LH321. Only LH321 has been morphologically described in the specification, as possessing a particular combination of traits as set forth in pages 9-12. LH321 has not been described with regard to its genetic complement, i.e. the particular collection of genes that confer all of the traits it exhibits. Other than four hybrids produced by crossing LH321 once with each of four different inbreds, no progeny from the cross of LH321 with any other plant have been disclosed. Even these four hybrids were only described on the basis of a few traits as listed in Tables 1-4 on pages 32-33 of the specification. Furthermore, the other non-LH321 inbreds utilized in these crosses were not described either morphologically or genetically.

The product of the method of claim 31, which would contain substantial amounts of non-LH321 genetic material, has not been characterized or described, because the collection of traits that it possesses has not been disclosed, and because it contains substantial amounts of non-LH321 genetic material which itself has not been described. The backcrossing method of claim 31 would minimize but not completely abolish the uncharacterized, non-LH321 genetic material present in the progeny, due to the maintenance of some non-LH321 genetic material in close proximity to the gene conferring the desired trait, which gene was obtained from the non-LH321 parent. The alternately recited method of pedigree breeding of claim 31 merely specifies that some record of breeding partners is kept, wherein LH321 was used at least once in at least one of several crosses with non-LH321 parents. The alternately recited method of recurrent selection of claim 31 merely indicates that selection over various generations of crosses occurred for some types of traits, including one or more non-LH321 traits conferred by non-LH321 genetic material. Both pedigree breeding and recurrent selection may involve multiple crosses with multiple uncharacterized, non-LH321 parents, over multiple generations. Thus, even more uncharacterized non-LH321 genetic material would be present in the progeny of pedigree breeding or recurrent selection, so that the products (i.e. progeny corn plants) of these methods would be even more uncharacterized with regard to genetic composition or morphological traits.

Furthermore, the molecular marker-mediated method of breeding alternately claimed in claim 31, including restriction fragment length polymorphisms, requires the use of a multitude of non-exemplified molecular markers. Not even one corn molecular

marker has been characterized or described in the instant specification, with regard to sequence, length or source. Thus, the claim reads on a method of using inadequately described products, rendering the method of using such products similarly inadequately described.

Claims 19, 21, 24, 30 and 31 read on processes involving the repeated outcrossing of the exemplified inbred to a multitude of genetically unrelated and uncharacterized corn plants for multiple generations (in the recitation in claim 31 of "pedigree breeding" and "recurrent selection", as discussed above). Unlike the backcrossing method, no attempt is made to reconstitute the genetic complement of the initial LH321 parent. Instead, LH321 may be used only in the initial cross, and then the progeny of this cross may be crossed to a multitude of unrelated and uncharacterized corn plants for up to 7 times (as recited in claim 21) or *ad infinitum* (as claimed in claims 19, 24, 30 and 31). The specification fails to disclose or describe any progeny resulting from such crosses, wherein said progeny could contain only a small portion of the LH321 genome, if any at all, and wherein said progeny would contain a majority of undisclosed and uncharacterized genetic material from a multitude of undisclosed and uncharacterized parents. Furthermore, no description has been provided for the progeny of such crosses with regard to even one morphological trait of said progeny containing a majority of non-LH321 genetic material.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed

subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the lack of written description in the specification regarding any of a multitude of non-LH321 parents to be used in a backcrossing breeding method or any other classical breeding method, one skilled in the art would not have recognized Appellant to have been in possession of the claimed hybrids or progeny plants as recited in claims 6 and 12-16. Furthermore, given the lack of an adequate written description of the claimed progeny plants, any method of using said progeny plants in further crosses, as claimed in claims 17-19, 21, 24, 30 and 31, would also be inadequately described. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111). See also *University of Rochester v. G.D. Searle et al*, Appeal No. 03-1304, decided 13 February 2004 (Fed. Cir. 2004), at pages 14-15, which states that the written description requirement is not limited to cases involving isolated genetic sequences.

Claims 26-28 are drawn towards LH321 plants further comprising a foreign gene (“transgene”) which was previously isolated as a piece of DNA, and then stably inserted into the corn genome by transformation. A review of claims 26-28 indicate that they

encompass a genus of corn plants, each species of which can differ in the morphological and physiological traits that they can express, since they would comprise different transgenes. Claims 26-28 also do not place any limitation on the trait conferred or affected by the single locus conversion. However, the specification does not describe identified or isolated single loci for all corn plant traits. While the specification, on page 20, paragraph [0090], through page 26, paragraph [0121], recites traits that are contemplated to be introduced into LH321, transgenes governing all of these traits have not been identified. Claims 26-28 also broadly encompass single loci that have not been discovered or isolated. Furthermore, the specification does not identify or describe even a single molecular marker which could be utilized in the breeding method of claim 31, and does not characterize the genome of LH321 or any hybrid derived therefrom in terms of molecular marker profile.

All transgenes that can be introduced into LH321 do not share the same structures (genetic sequences) and functions, and each transgene would have a different effect on the LH321 plant. No guidance has been provided which correlates the structure of all transgenes with their function of conferring particular traits.

The specification fails to provide an adequate written description of the genus of transgene or molecular marker sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, or assaying plants for their presence, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of

the claimed transgenic corn plants or methods of making or using them at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Appellant's Arguments and Examiner's Response:

In the Appeal Brief submitted 04 December 2003, Appellant again argues that the hybrid seeds and plants are described because they have LH321 as a parent and therefore contain a copy of the same genome as corn plant LH321, and that they have inherited half of their genetic material from LH321 (Appeal Brief, page 7, bottom paragraph).

First, the Examiner would like to address a statement made by Appellant that may be a point of confusion. Appellant states, "All of the claimed hybrid plants having LH321 as a parent will therefore contain a copy of the same genome as corn plant LH321" (emphasis added; Appeal Brief, page 7, bottom paragraph). By stating that the hybrids contain the same genome as LH321, this statement can be interpreted to mean

that the entire genome of any of the claimed hybrids is identical to the entire genome of LH321. Since inbred corn plant LH321 must be crossed with a different corn plant to produce the claimed hybrids, the claimed hybrids cannot have entirely the same genome as LH321. It appears to the Examiner that Appellant did not intend to indicate that all of the claimed hybrid plants have entirely the same genome as LH321, as Appellant then immediately states, "That is, because LH321 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant LH321..." (emphasis added), which correctly indicates that all hybrids would inherit one-half, not all, of their genome from LH321.

The Examiner maintains that the claimed hybrids will not have the same morphological and physiological characteristics as LH321. LH321 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are also different from those expressed by LH321. That all hybrids will inherit half of their alleles from LH321 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of LH321 with any of the traits that it expresses. Further, the claimed hybrids will inherit one allele for every gene from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from LH321, or how the products of those alleles, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the

combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and on the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from LH321 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.

For example, if LH321 carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the inheritance of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is clear that the mere provision of one-half of the hybrid's genetic complement being inherited from LH321 is woefully inadequate to describe the resultant hybrid, either genetically or morphologically.

Appellant also argues that the entire genetic contribution of corn plant LH321 is described by way of deposit of seed of LH321 with the ATCC, and believe that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishes them from other plants. In support of their argument, Appellant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material

(Appeal Brief, paragraph bridging pages 7 and 8; page 9, penultimate paragraph through page 10, penultimate paragraph). However, in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. As in *Enzo*, here the deposited inbred does not correspond exactly to the claimed hybrid. However, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited LH321 seed. The function of the plant grown from a LH321 seed is correlated with the structure of its entire genome, not just one half. The function of the claimed hybrid plants grown from the claimed hybrid seeds is correlated with the structures of their entire genomes, not just the alleles inherited from LH321. Further, half of the alleles of the hybrid are inherited from the other parent, and are not described by the deposited LH321 seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited LH321 seed, as discussed above.

Appellant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Appellant argues that here, all of the members of the claimed genus of hybrids having LH321 as one parent share the identical feature of having the genetic complement of LH321 (Appeal Brief, middle paragraph of page 8). For the reasons

explained above, the hybrids do not have the entire genetic complement of LH321, but only half that complement. In *Eli Lilly*, the members of the genus shared a common function. In the instant application, the specification does not describe the functions (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the functions of the hybrids with the structure of the genetic complement of LH321. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Appellant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred LH321 with any and all other inbred or hybrid corn plants.

Appellant continues, arguing that the second plant that is used to make the claimed hybrids is irrelevant, as any second plant capable of reproduction may be used to make the hybrid. Appellant argues that the claims cannot be said to lack written description for the second genetic complement, particularly given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art. Appellant points to the more than 300 patents issued for corn varieties as support, and argue that any one of these corn plants could be used to produce an F1 hybrid plant having LH321 as one parent, and each of these would share the genetic complement of LH321 (Appeal Brief, paragraph bridging pages 8-9 and page 9, 1st full paragraph).

However, again, it is the interaction of the products of all of the alleles of the claimed hybrids, not just the products of the alleles inherited from LH321, which determine the traits of the claimed hybrids. Each parent contributes one set of chromosomes to the hybrid progeny, and each set of chromosomes comprise one allele

for each gene at every locus in the genome, wherein alleles are alternate forms of the same gene that occur at a given locus. A phenotypic trait of the plant results from the expression of the two sets of alleles. The resulting phenotype of the plant depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with other gene products in the genome. Some alleles of the same gene are dominant to others. The interaction of nonallelic genes by epistasis also affects the phenotype, and quantitative traits are determined by the combined effects of multiple genes. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrid's morphological and physiological traits, one cannot correlate the alleles inherited from LH321 alone, with the phenotype of the hybrid progeny. Thus, the deposit of LH321 seeds and the recitation of some phenotypic characteristics of corn plant LH321 is not sufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing LH321 with a second, distinct corn plant. Appellant would have one believe that only half of a genome is sufficient to describe a plant. Yet, if only half of the genome of LH321 was deposited, it would not have been enough to describe its full genome, as discussed above.

Appellant next argues, in response to the Examiner's previous arguments that the morphological and physiological characteristics of the hybrids have not been described, and that the manner in which the genes inherited by the hybrids would be expressed or interact has not been shown, that the Examiner's position "misses the point that Appellants have gone one step further by describing the claimed hybrid plants at the genetic level." Appellants assert that "[a] better description could not be made

than at the genetic level” (Appeal Brief, paragraph bridging pages 10 and 11).

However, again, Appellant is attempting to describe the claimed hybrids by only half of their genome. Appellant has deposited LH321 seed and, by extension, the LH321 genome, since the cells of the LH321 seed contain the LH321 genome. The claimed hybrids inherit only half of this genome, and the claimed hybrids do not have all of the same functions as those possessed by LH321. Given the genetic composition at each locus of the second inbred chosen as the hybrid’s parent, the resultant hybrid may even have fewer than one-half of the traits exhibited by LH321.

Appellant repeats his argument that a further description of the claimed hybrid plants is provided in the specification by way of the four hybrids disclosed in Tables 1–4 of the specification, and believes that these four plants are representative of all hybrids produced using LH321 as one parent, each of which comprise the genetic complement of the parent corn plant (Appeal Brief, paragraph bridging pages 11 and 12). Appellant argues that this information combined with the descriptions of LH321 and the shared structure among the hybrids is more than adequate to describe the claimed subject matter. However, again, hybrids that do not share both of the same parents will not have the same traits. The performance comparisons of four hybrids produced by crossing LH321 with four other plants cannot be extended to any other hybrid plant that does not have both of the same parents, and are not representative of *all* hybrids produced using LH321 as only one parent and using a multitude of genetically and morphologically uncharacterized and unrelated corn plants as a second parent.

Regarding the description of transgenes and corn plants containing them, Appellant argues that the Examiner supposedly ignored evidence submitted in a prior response that the specification recites numerous single locus traits with a publication reference or patent number. Appellant goes on to provide several examples (Appeal Brief, page 5, 1st full paragraph to page 6, 1st paragraph). While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that certain genes have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability, as stated above. If such single loci have not been discovered or isolated, Appellant cannot be in possession of LH321 plants transformed with gene(s) conferring these traits. The claims broadly encompass plant LH321 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Appellant cannot be in possession of plants further comprising single loci that have yet to be identified. It is also noted that the Examiner is not asking Appellant to identify each and every gene known to man by name, but to identify the types of single loci, that alone control a trait, that have been identified. For example, many genes or single loci were known in the prior art that confer disease resistance, or herbicide resistance. In the Office action mailed 13 January 2003, on page 9, it was suggested that the claims be amended to recite the types of single gene loci, not individual or specific loci names. This suggestion was not adopted by Appellant.

In addition, Appellant has not provided any structural sequences common to all of the transgenes which were correlated with function. Furthermore, Appellant has not described any transformed inbred plant which would retain all of the features of the exemplified inbred except for the introduced transgene-encoded trait. Appellant has only described the exemplified inbred with respect to a collection of traits. It is unclear how the introduction of a multitude of non-exemplified transgenes, encoding a multitude of proteins or enzymes or inhibitory RNA products which would be involved in a multitude of metabolic pathways resulting in a multitude of traits, would interfere with one or more of these traits. Such interference would result in the production of a multitude of corn plants with a different collection of traits than the exemplified inbred. Since no genetic characterization of the inbred was initially provided, and since the only identifying description of the inbred, namely the unique *collection* of traits, has now been obliterated, the genus of corn plants transformed with a multitude of non-exemplified transgenes would have been inadequately described. It is noted that claims limited to a method of producing a transgenic corn plant comprising transforming the exemplified inbred with single, known transgenes recited in the specification, and the resultant corn plant produced by that process, would in fact be adequately described, as stated in the last Office action.

Appellant argues that techniques for introducing single locus traits by genetic transformation were well known (Appeal Brief, paragraph bridging pages 6 and 7). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not

reduce to practice the product itself. See *Bayer v. Housey*, Appeal No. 02-1598, (Fed. Cir. 2003), decided 22 August 2003, penultimate page: "processes of identification and generation of data are not steps in the manufacture of a final [drug] product".

Appellant urges that the rejection of claim 6 as lacking an adequate written description is improper, given the availability of cytoplasmic and nuclear male sterility genes and their transfer into various corn genetic backgrounds (Brief, page 5, second full paragraph). The Examiner maintains that claim 6 as written is drawn to a corn plant which simultaneously is male sterile and male fertile, as discussed above in the rejection under 35 USC 112, second paragraph. One skilled in the art would not have recognized Appellant to have been in possession of such a plant at the time the invention was made.

Appellant urges that rejections of method claims as lacking an adequate written description are not in compliance with the Written Description Guidelines of 05 January 2001 (page 12 of the Brief, bottom paragraph through page 13 of the Brief, first full paragraph). Appellant is directed to *University of Rochester v. G.D. Searle & Co., Inc.*, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L, decided 05 March 2003, at page 18, bottom paragraph, which teaches that method claims are properly subjected to a written description requirement if the starting material which requires that method is itself inadequately described. See also the rulemaking proceedings involved in creating the written description guidelines, 64 Fed. Reg. 71427, 71428, comment No. 4.

35 USC 112, first paragraph, enablement

Claims 6, 12-19, 21, 24, 26-28 and 30-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards any hybrid corn seed produced by the process of crossing the inbred corn plant LH321 with any second, distinct, inbred corn plant, and any hybrid corn plant produced by growing said hybrid corn seed (claims 12-16); methods of using the hybrid (claims 17-18); methods of repeatedly crossing LH321 with any other undefined non-LH321 parent over multiple generations (claims 19, 21, 24 and 30-31); any inbred corn plant produced by growing seed of inbred corn plant LH321. Claim 14 is drawn to a seed produced on a hybrid plant of claim 13, wherein the hybrid plant was produced by crossing LH321 to a different parent, and wherein any seed produced by said hybrid plant of claim 13 would have to be produced by another round of crossing to another non-LH321 parent; thus, claim 14 is actually drawn to a descendant of LH321 which has undergone multiple generations of crossing to non-LH321 parents. The claims are also broadly drawn to corn plants grown from LH321 seed wherein said plant further comprises any transgene of any sequence and conferring any trait (claims 26 and 28); a method of producing a transgenic corn plant comprising crossing a corn plant which has been transformed with any transgene of any sequence and conferring any trait (claim 27); and any inbred corn plant which

comprises any gene of any sequence which confers male sterility (claim 6), which male sterile plant may be produced by any method including outcrossing to a non-LH321 donor parent that contains a gene for male sterility in addition to many other undesirable genes. Claim 6 also implies that the male sterile corn plant simultaneously contains all of the genetic and morphological characteristics of LH321, which is in fact male fertile, as discussed above. Claim 31 is also drawn to the use of a multitude of molecular markers, i.e. small pieces of DNA which are adjacent to/correlated with the presence of a particular gene conferring a particular trait, including restriction length fragment polymorphisms.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences ("transgenes") conferring a multitude of traits, as recited in claims 26-28. No guidance has been provided for identifying methods of using the resultant corn plants containing a multitude of unspecified transgenes conferring unspecified, if any, traits. Additionally, no guidance has been provided for *how to make* an LH321 corn plant which is simultaneously male fertile and male sterile, as claimed in claim 6. Furthermore, no guidance has been provided for *how to make* any corn molecular genetic markers, or for *how to use* the unmade markers, as encompassed by claim 31.

In addition, no guidance has been provided for the introduction of any single desired trait from a multitude of non-disclosed and uncharacterized donor breeding partners into LH321, by backcrossing as claimed in claim 31 or by any other means as claimed in claim 30, wherein the introduction of the desired trait should result in

successful expression of the desired trait but should not interfere with the expression of the remaining LH321 traits. Furthermore, no guidance has been provided for preventing the introduction of unwanted genetic material conferring undesirable agronomic traits from the donor breeding partner into LH321. No guidance has been provided for the identification of any molecular genetic markers such as restriction fragment length polymorphisms as claimed in claim 31, wherein said genetic molecular markers have been demonstrated to be linked to corn genes conferring agronomically desirable traits, or their use to breed and obtain improved corn genotypes using LH321 as the starting material. No guidance has been provided regarding the morphological or genetic composition of a multitude of non-exemplified breeding partners for crossing with LH321, either in a single cross to produce a hybrid corn plant as claimed in claims 12-13 and 15-16, or in multiple crosses with non-LH321 parents over multiple generations, as claimed in claims 14, 19, 21, 24, 30 and 31. Given the lack of guidance regarding the genetic composition or morphological traits of the non-disclosed breeding partners, no guidance has been provided for methods of using the resultant progeny plants with unknowable morphological and genetic characteristics. Furthermore, no guidance has been provided for methods of using hybrids produced by crossing LH321 with a multitude of non-disclosed parents, as claimed in claims 17-18, since the hybrids themselves have not been reduced to practice or characterized morphologically or genetically, throughout the broad scope of the claims.

As discussed above, traditional plant breeding involves the crossing of two parents which contribute half of their entire genetic composition in an uncontrolled,

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random manner. A cross between LH321 and a non-LH321 parent, such as a weedy corn relative which possesses a gene for insect resistance, will result in a variety of progeny plants, each containing a different combination of half of the (thousands of) genes from each parent. Many of the traits found in LH321 will not be expressed by such progeny, and such progeny will express many traits conferred by the genes from the non-LH321 parent. If the non-LH321 parent is another agronomically desirable breeding line, the resultant progeny may contain a collection of traits which might be useful in some growing environments, such as early or late flowering, but not in the growing environment for which LH321 was intended. If the non-LH321 parent is a weedy relative of corn, the resultant progeny may contain many traits which are agronomically undesirable in any environment, such as low seed yield, small kernel size, small cob size, high susceptibility to stalk breakage, etc. Following the initial production of progeny, plant breeders select those progeny which exhibit more desirable traits and fewer undesirable traits, and perform more crosses with these progeny, in the hopes that the genes conferring the desirable traits will be retained and transmitted to future generations, while the genes conferring the undesirable traits will be lost and not transmitted to future generations. The process of gene transmission following pollination is random, and the selection for desired traits results in the transmission of entire chromosomes containing many unknown or undesirable genes which are in close proximity to (or "linked" to) genes conferring desirable traits. Successful production of a classically bred variety depends upon the success of the selection for the desirable trait in each generation, the ability of the gene(s) conferring

the desired trait to be expressed when it interacts with a variety of other non-exemplified genes in other genetic backgrounds, and the ability to select against undesirable traits conferred by genes which are linked to the genes conferring the desirable trait.

It is the *combination* of traits listed on pages 9-12 of the specification, rather than any *individual* trait or its expression, which confers patentability to LH321, and for which Appellant has taught a use. These traits include 75 days from emergence to 50% of plants in flower (a measure of flowering time and subsequent corn kernel development in a particular climate with a particular length of pre-frost growing season), average plant height of 192 cm (which may be adapted for growing areas with high or low wind conditions), leaf sheath pubescence of 2 on a scale of 1-9 (where relatively hairless leaves might confer an advantage in humid growing environments prone to fungal disease, but which would confer a disadvantage in dry environments because more water vapor would evaporate from the leaf surface), husk tightness of 5 on a scale of 1-9 (where tight husks, which protect the kernels below, may be advantageous in growing environments with much wind or hail, but which would be disadvantageous to the consumer and so should be avoided when not needed), straight alignment of rows of kernels (which would be desirable for corn on the cob but unnecessary for corn to be removed from the cob for processing in canned or frozen form), roundness of kernels (which would affect their use as popcorn, corn on the cob, or processed canned or frozen corn), and endosperm starch (which would affect the kernels' use as sweet corn or as a source of corn syrup for sweetening processed food). These traits also include

white cob, green-yellow pollen, and green-yellow silks (female flowers), which combination of traits could be diagnostic for LH321.

It is not clear that single loci may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety, even if followed by backcrossing to the original recipient parent LH321, as claimed in claim 31.

Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single locus conversion plant with a desired trait (column 3, lines 26-46). The gene conferring the desired trait may be properly expressed in some genetic backgrounds, but not expressed in other backgrounds, so that the trait would not be predictably conferred. Thus, a gene conferring disease resistance in one donor variety of corn may not function properly when transferred into LH321, due to the interactions with all of the other LH321 genes that were not present in the original donor variety.

Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion but otherwise maintaining all of

the desired genes and traits of the recipient parent, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Linkage drag refers to the close proximity on the chromosome of genes conferring undesirable traits to a gene conferring a desirable trait. Due to such close proximity, it is virtually impossible to remove the genes conferring the undesirable trait from progeny of crosses which were selected for the desirable trait. The situation becomes even more complex when it involves traits such as seed yield which are affected by multiple genes on multiple chromosomes, i.e. "quantitatively inherited" traits.

Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Epistasis refers to the unpredictable interaction of various genes with each other. Such epistasis may result in the inhibition of one gene by another, so that a gene conferring insect resistance, which functions in a particular donor plant, would not function in LH321 or a progeny thereof, due to the presence of other genes in LH321 or the progeny which inhibit the function of the insect resistance gene. In quantitative traits, which are governed by the combined action of many genes, each conferring a small effect on the trait, the situation is even more

pronounced. In quantitative traits such as yield, high yield of 200 bushels per acre may be the result of the contribution of 20 genes on different chromosomes, each conferring an incremental yield increase of 10 bushels per acre, when acting in an additive fashion. Due to epistatic interactions with other genes in other genetic backgrounds, even if all 20 genes were present, they would not act additively to cause a yield of 200 bushels per acre. Perhaps half of the genes would be inhibited, giving a low yield of only 100 bushels per acre. Furthermore, some of the 20 genes might not even be transmitted to the progeny, due to random gene segregation as well as the selection against undesirable traits conferred by genes linked to some of the 20 high yield genes.

In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed plants which differ from LH321 only in comprising a single locus conversion and by the expression of a single trait. It appears that even backcrossing attempts, as claimed only in claim 31, would result in the production of plants with many undesirable traits which are conferred by genetic material linked to the gene conferring the trait of interest. If backcrossing to LH321 were not attempted, as claimed in claims 19, 21, 24 and 30, even more undesirable, non-LH321 genetic material would remain in the progeny plants, further obliterating the desirable collection of traits exhibited by LH321. Every time that LH321 is crossed to a non-LH321 parent, half of the genetic contribution of LH321 is lost. The resultant progeny of the process of claim 21, which involves an initial cross of LH321 with another plant (as recited in claim 19 on which it depends), and which then involves

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up to seven additional crosses with non-LH321 plants, would have as little as one-sixteenth or 6.25% of its genetic material derived from LH321, and the remaining fifteen sixteenths or 93.75% of its genetic material would be comprised of undefined genetic material from the other non-LH321 parents involved in the crosses. The progeny of the crosses of claims 19 and 30 do not specify a finite number of crosses, following the initial cross of LH321 to a non-LH321 parent, so that the resultant progeny may retain little or any LH321 genetic material. No guidance has been provided regarding the use of said progeny, which contain less and less LH321 genetic material, and which therefore exhibit fewer and fewer LH321 traits.

Regarding the use of transgenes, claims 26-28 do not specify the sequence of the transgene; the source of the transgene which may be from bacteria, fungi, animals or plants; or the encoded product, such as a multitude of proteins or enzymes, or reverse-orientation RNA molecules which inhibit the expression of other genes, etc. These claims do not even specify the traits which result from the introduction and successful expression, if any, of the transgene. (Note that the Examiner has previously suggested that claims should be submitted which at least specify the traits encoded by the genes, when such genes encoding such traits have already been isolated by other skilled artisans, such as herbicide resistance, disease resistance, insect resistance, waxy starch, etc.) However, the specification does not enable transforming LH321 cells with all transgenes. As broadly interpreted, the claimed plants and method encompass introducing any type of transgene into LH321, including those that have not been isolated at the time the application was filed. The prior art shows that hundreds of

nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed. One skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell. However, the claims do not place any limit on the transgenes to be introduced, and encompass transgenes for plant traits that have yet to be isolated. For example, isolated genes whose products confer yield enhancement are not known in the prior art. One skilled in the art cannot practice the claimed method and produce the claimed plants if the nucleotide sequences whose product confer a desired trait has not been isolated at the time the instant invention was made.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Also, the pre-selected DNA, as broadly interpreted, includes isolated genes whose functions are not known. If the effect of expressing a transgene in LIZL5 were not known, one skilled in the art would not know *how to use* the transformed plant. See also Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Further, the effects of transgene expression on the traits expressed by untransformed LH321 are unknown. The specification does not teach one how to use a transformed LH321 plant if all of the morphological and physiological traits of LH321 are

not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Appellant's Arguments and Examiner's Response:

Addressing the issue that the specification does not teach one skilled in the art how to use the claimed transgenic plants when the transgenes aren't identified, Appellant first notes that the introduction of DNA into a cell occurs without regard to the nucleic acid transformed, and that claims 26-28 are not drawn to transgenes conferring a particular trait (Appeal Brief, paragraph bridging pages 14 and 15). However, the Examiner never doubted that the introduction of DNA into a cell occurs without regard to the nucleic acid transformed, or that methods to transform corn were known in the prior art. Instead, the Examiner's position is that the specification fails to teach one skilled in the art *how to make* transgenic corn plants *when using yet-to-be-isolated transgenes*, as encompassed by the claims which fail to specify any particular transgene. One cannot make a transgenic plant with types of transgenes that have not been isolated, such as those that confer yield enhancement or enhanced yield stability. Furthermore, the specification fails to teach one skilled in the art *how to use* corn plants which have been transformed with *unspecified* transgenes *conferring unspecified traits*, if any, to the transformed plant.

Further, the transgene may encode any product having any function, and can therefore affect the other traits expressed by LH321. For example, if the single locus encodes a transcription factor, the expression of numerous genes may be affected,

which in turn would affect numerous traits expressed by LH321, including yield, flowering date, maturity date, etc. In such a scenario, one may not obtain a plant having all or even most of the desired morphological and physiological traits of LH321, in addition to the trait conferred by the transgene. Alternatively, the transgene may encode an enzyme involved in more than one metabolic pathway, i.e. an enzyme involved in the production of a protein involved in disease resistance as well as a protein involved in yield. Thus, a corn plant with this gene may have increased disease resistance but an agronomically unacceptable yield level. The specification fails to teach one skilled in the art how to use such a plant.

Furthermore, the specification fails to enable the production of corn plants whose genome would be identical to LH321 while simultaneously containing a transgene not initially present in LH321, as claimed in claim 26. See the rejection of claim 26 under 35 USC 112, second paragraph, above.

To make the distinction, an amendment is again suggested in which types of transgenes, not any specific transgene by name, contemplated by the specification, be inserted into parent plant LH321. For example, many herbicide resistance genes or plant virus resistance genes were known in the prior art. The claims need not identify each and every such gene by name, but may simply indicate that the transgene may be an herbicide resistance gene or a plant virus resistance gene. If the gene is taught and known in the prior art, one skilled in the art would know how to make and use the claimed transgenic plant. As also indicated above, the submission of transgenic claims in an alternating method of making/product-by-process format would obviate the aspect

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of this rejection regarding the enablement of a plant that is simultaneously transgenic and non-transgenic.

Appellant urges that the enablement rejection regarding the production of male-sterile plants is improper, given the decades-long availability of genes and breeding techniques just for this purpose (Appeal Brief, page 15, middle paragraph). The Examiner does not dispute this, but merely maintains that techniques for producing a plant which is simultaneously male fertile and male sterile are not available. Amending claim 6 to overcome the rejection under 35 USC 112, second paragraph, would obviate the rejection of this claim as lacking enablement.

Turning to the aspect of the rejection concerning the enablement of corn plants derived from variety LH321 and produced by classical breeding methods involving non-LH321 plants as breeding partners, including backcross breeding methods to produce LH321 plants comprising a single locus conversion, Appellant argues that, as noted before, no basis has been given to show that the references cited by the Examiner to support his position have any relevance to corn plants. Appellant urges that corn breeding is much more well-developed than the breeding of petunias, sugar beets or tomatoes. Appellant further urges that references that pertain to dicotyledonous, or broad-leaved, plants such as tomato, petunia and sugar beet are inapplicable to monocotyledonous, or narrow-leaved plants such as corn, per *Plant Genetic Systems v. Dekalb Genetics Corp.* Appellants argue that there is no support for the Examiner's assertion that the cited references concerning petunias, sugar beets, and tomatoes would apply to corn, and that the Action attempts to require Appellants to show why this

is not true. Appellant argues that it is the burden of the Office to support its rejections (Appeal Brief, page 15, bottom paragraph through page 17, top paragraph).

The rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome. Linkage drag appears to be a phenomenon that occurs in all plant types. Examples are lacking in the prior art of plants in which linkage drag does not occur. There is no evidence that corn is exempt from this universal trend. Linkage drag, for reasons embellished in the previous Office action and repeated above, would prevent one skilled in the art from making the LH321 plants comprising single locus conversions as currently claimed in claim 31 which recites backcross breeding. Furthermore, linkage drag would result in the maintenance of numerous non-LH321 genes, conferring numerous agronomically undesirable traits, in any progeny produced by crossing LH321 only a single time, followed by continued generations of outcrossing to non-LH321 parents, as claimed in claims 19, 21, 24 and 30. The cited references demonstrate the *widespread* phenomenon of unpredictability, throughout cultivated plant species, in utilizing classical breeding by crossing two different plants in order to transfer desired traits while preventing the transfer of linked deleterious traits. The fact that these references are not specific to corn is immaterial. Appellant has not provided any evidence that this phenomenon does not occur in maize, and has not provided any guidance to overcome this unpredictability.

Regarding the issue of monocotyledonous versus dicotyledonous plants, the Examiner notes that the cited case law dealt with methods of plant transformation and

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plant cell tissue culture, wherein said methods had been historically more developed for dicots than for monocots, particularly at the time that the applications in question were filed. However, in the instant case, the Examiner relied upon references dealing with three different dicotyledonous plant species in order to demonstrate the unpredictability inherent in particular aspects of *classical plant breeding*, involving neither transformation nor tissue culture. Although corn breeding may be well-developed with regard to the acreage devoted to new corn varieties, the problems that plague other crops regarding the transfer of discrete genes conferring discrete traits, while otherwise retaining the virtually complete genetic fidelity of the original recipient parent, appear to be equally applicable in corn.

Appellant urges that claims drawn to hybrids and methods of their use were improperly rejected as non-enabled, since the method of making the hybrid as in claim 11 were not subject to this rejection, and since the choice of the non-LH321 parent would not in any way hamper the ability of this parent to be crossed with LH321 in order to produce a hybrid corn plant (Appeal Brief, page 17, bottom three paragraphs).

The Examiner maintains that claim 11 is enabled to the extent that it reads on a method of using the product LH321. Since LH321 has been described regarding its morphological traits, a method of using it to cross one time with another plant is also enabled. However, the resultant plant as claimed in claim 12 is not enabled because the specification does not teach *how to use* such a hybrid. As the hybrid comprises only half of the genetic complement of LH321, and possesses a multitude of unknown traits, one skilled in the art would not know how to use such a plant with unspecified traits.

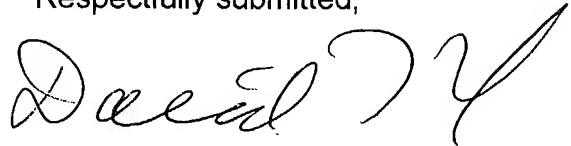
Furthermore, if the second parent were a weedy corn relative or another type of non-agronomic corn variety, the resultant hybrid product would be even less useful.

Limitation of claim 12 to recite the four exemplified non-LH321 parents taught in the specification would obviate the rejection of claims 12 and 13. However, claim 14 is inherently drawn to a method comprising crossing the hybrid of claim 13 with another, non-LH321 plant of unspecified genetic and morphological constitution. The *production* of seeds *on a plant* requires pollination, either with itself or with another plant of different genetic constitution, and so is not trivial, as asserted on page 17, second full paragraph. The rejection of claim 14 thus cannot be obviated by amendment.

Appellant urges that the enablement rejection over processes of using LH321 in other classical breeding methods is improper, given the enablement of LH321 itself and the knowledge of the claimed breeding methods by the artisan of ordinary skill (Appeal Brief, page 18, middle paragraph). The Examiner maintains that since the genetic or morphological complements of the second and subsequent breeding partners have not been identified, the genetic and morphological traits of the resultant products of those breeding processes are unknowable. Thus, one skilled in the art would not know *how to use* the products of such methods.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



David T. Fox
Primary Examiner
Art Unit 1638

February 21, 2004

Conferees



Bruce Campbell
Supervisory Patent Examiner
Art Unit 1661



Amy Nelson
Supervisory Patent Examiner
Art Unit 1638

Fulbright & Jaworski LLP
600 Congress Avenue
Suite 2400
Austin, TX 78701